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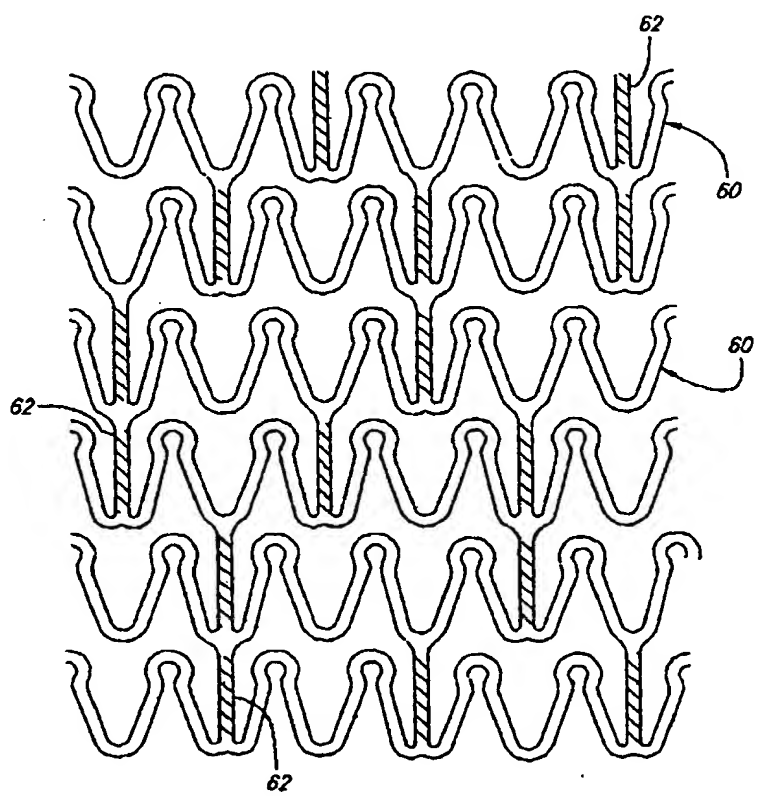
(54) Title: COMPOSITE SUPER ELASTIC/SHAPE MEMORY ALLOY AND MALLEABLE ALLOY STENT

(57) Abstract

Composite stent structure defined by openings in a tubular member formed from one or more layers of a biocompatible, malleable metal and one or more layers of a superelastic or a shape memory alloy. The layers are co-drawn or compression-fit together.



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COMPOSITE SUPER ELASTIC/SHAPE MEMORY ALLOY AND MALLEABLE ALLOY STENT

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to expandable endoprosthesis devices, generally called stents, that are adapted to be implanted into a patient's body lumen, such as a blood vessel, to maintain the patency thereof. In particular, the invention relates to metallic stents formed from a composite structure comprising discrete layers of super elastic or shape memory alloys and biocompatible, malleable alloys.

Description of the Prior Art

Stents are generally cylindrically shaped devices that function to hold open and sometimes expand a segment of a blood vessel or other anatomical lumen. Stents particularly are suitable for use to support and hold back a dissected arterial lining which can occlude the fluid passageway therethrough, or to maintain the patency of a portion of a blood vessel that has been subjected to an angioplasty procedure.

A variety of devices are known in the art for use as stents and have included coiled wires, slotted tubes, and adjacently connected cylindrical elements in a variety of patterns that are expanded after being placed intraluminaly on a balloon catheter; helically-wound coiled springs manufactured from a thermally expandable metal; and self-expanding stents inserted in a compressed state and subsequently allowed to expand at the intraluminal target site by withdrawing the compressive force, such as provided by an overlying sheath. One of the difficulties encountered using prior stents is providing a stent structure that is longitudinally flexible to easily traverse the tortuous pathways of the human vasculature and which can be readily and uniformly expanded, but that will resist permanent deformation due to the compressive forces exerted by the body lumen itself or by external forces on the body lumen once the stent is deployed and expanded. Resistance to permanent deformation can be especially desirable, for example, in stents deployed within a patient's carotid artery, where a stent may be subjected to additional forces generated by

the patient's head and neck movements, or by the pillow, arm, or other head rest used by the patient when sleeping, or by blows to the patient's neck or head.

A number of prior art stents have attempted to address the problem of meeting the various requirements imposed upon them by employing structures comprising different materials selected for their various, desirable physical characteristics. For instance, U.S. Pat. No. 5,749,880 to Banas et al. discloses a stent-graft comprising a tubular stent structure with openings through its wall surfaces to permit radial expansion and circumferentially adjacent layers of polytetrafluoroethylene (ePTFE) covering the inner and outer wall surfaces of the stent. The ePTFE coverings are sintered to the tubular stent to bond around and through the wall surfaces of the tubular stent. Upon expansion of the stent, the ePTFE coverings expand as well to prevent exposing the stent to body tissue or fluids. The goal of this stent therefore is to enhance the biocompatibility of the stent rather than to enhance its mechanical properties.

U.S. Patent No. 5,725,570 to Heath discloses tubular prostheses that are woven from a filament consisting of a metal outer layer with an exposed outer surface and an inner core comprised of a different material than the outer layer. The outer layer is selected from superelastic alloys such as nickel-titanium (nitinol) or stainless steel, and the core is a high density, radiopaque metal such as tantalum. Stents formed from such a filament are said to exhibit substantially the elasticity properties of a solid nitinol filament, but with higher radiopacity. However, such a filament does not impart increased structural strength to the filament, and does not alleviate problems associated with woven wire stents such as lower than desirable crush resistance. Further, the filament experiences a wide range of tension and compression as it is bent during weaving and placement of the stent, as well as during use.. These forces are experienced to different degrees by the inner core and the outer layer and could be a potential source of failure due to the different responses exhibited by the dissimilar metals in the core and in the outer layer.

Another type of device is, for example, disclosed in U.S. Patent No. 5,769,882 to Fogarty et al., and comprises essentially a tubular prosthesis body with an overlying sealing layer to provide a fluid-tight seal between the exterior surface of the prosthesis and the inner wall of the body lumen. The tubular body is disclosed as being comprised of two

or more different materials, such as organic polymers and metallic elements, to provide different characteristics to the body, such as shape memory, drug delivery, bioabsorbability, and radiopaqueness. The specification discloses that such different materials can be incorporated in a variety of ways, such as different interwoven helices and braids, and include tantalum, nitinol, polyester, and PTFE. Again, this type of device appears limited to woven structures, and is directed to structures wherein the individual filaments are comprised of a single homogeneous material. Further, this type of device does not appear to address the goal of increased structural strength.

In light of the above, it becomes apparent that there remains a need for a stent providing increased structural strength while exhibiting substantial elasticity to resist permanent deformation that might occur during intravascular deployment and use.

SUMMARY OF THE INVENTION

The present invention addresses the above-mentioned needs by providing a tubular stent structure manufactured from a metallic tube comprising one or more layers of a biocompatible, malleable material co-drawn with, or compression fit onto, one or more layers of a superelastic, or shape memory alloy, material. The stent is manufactured by forming various patterns into the wall of the tube to create radially expandable, interconnected elements. The patterns may be formed by various methods, such as laser cutting, mechanical grinding or chemical etching, or a combination of these methods.

In use, the stent is introduced into the vasculature of the patient and deployed at the target site using well-known balloon angioplasty techniques. Once expanded, the stent exhibits, due to the malleable material layer, structural strength and crush resistance to support the vascular wall and to maintain the patency of the vessel. The stent additionally exhibits enhanced resistance to permanent deformation due to the superelastic material layer that proceeds to spring back to a predetermined expanded size and shape whenever subjected to a compressive force.

A stent formed according to the method of the present invention provides an axially flexible structure that, when expanded, offers radial strength and superior resistance to

permanent deformation. The stent is manufactured economically using known methods and materials, and comprises a significant improvement to the long-term safety of stents and stent-like devices.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a cross-sectional view depicting a tube for making a stent according to the present invention;

FIG. 2 is a plan view depicting a flattened section of a stent pattern made according to the present invention; and

FIG. 3 is a plan view depicting a flattened section of an alternative embodiment stent pattern made according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to Figure 1, wherein a preferred embodiment of a tube for manufacturing a stent according to the present invention is shown, a cylindrical tube 10 is comprised of a co-drawn outer layer 30 and an inner layer 32. The embodiment of the cylindrical tube 10 shown in FIG. 1 is drawn in a cylindrical configuration with an inner lumen 40 defined by an inner exposed surface 34 of the inner layer 32 and extending axially through the tube 10.

The inner layer 32 may be disposed within the outer layer 30 by a variety of methods. A preferred method entails co-drawing the inner layer and the outer layer, resulting in a tight, continuous interface 36 between the inner and the outer layer. Details of the co-drawing process may be found in, for instance, Volume 14: Forming and Forging of the Metals Handbook®, Ninth Edition, Copyright 1988 by ASM International. An alternative method involves compression fitting the outer layer onto the inner layer, such as

by disposing the inner layer on a fitted mandrel of a preselected shape for support, sliding the outer layer over the inner layer, and subjecting the assembly comprised of the two layers to a compressive force sufficient to collapse the two layers over the mandrel to assume the shape of the mandrel, following which the tubular body thus formed by the two layers can be removed from the mandrel and further processed as described elsewhere in the disclosure.

With continued reference to FIG. 1, the outer layer 30 preferably is formed from a malleable metallic material that exhibits sufficient strength when expanded to maintain the patency of the vessel wall. A preferred material for the outer layer is stainless steel, which is well suited for intravascular applications due to its biocompatibility and structural strength. Other materials that may be employed in forming the outer layer include cobalt, platinum, iridium, gold, magnesium, titanium, tantalum, and platinum-iridium alloys.

The inner layer 32 is formed from an elastic metallic material that will spring back to its original size and shape whenever subjected to a deforming force. The inner layer may therefore be manufactured from spring steel or from alloys exhibiting superelastic or shape memory properties. Articles manufactured from such alloys may be deformed from their original shape into a different configuration that is heat unstable, and upon the application of heat will revert to the original configuration. Certain shape memory alloys, including superelastic nickel-titanium (NiTi) (nitinol) or copper-zinc-aluminum (CuZnAl) alloys that are well known in the art, can be deformed through the application of stress to the article of manufacture and will revert to their original shape upon removal of the stress in a phenomenon generally referred to as stress induced martensite (SIM), thereby eliminating the need for alternately cooling and heating the article. SIM shape memory alloys that are stressed at temperatures between where the alloy first begins to transform from austenite to martensite, and the maximum temperature at which martensite can occur, deform elastically up to a critical stress and then continue to deform through the formation of SIM. When the deforming stress is removed and the alloy is at a temperature above that at which it starts to revert back to austenite, the alloy will attempt to return to its original shape. The temperature at which the alloy begins to revert to the stable austenite phase varies with the composition of the alloy, and it obviously is preferable for the practice of

the present invention that a SIM shape memory alloy selected for making the inner layer 32 be one that reverts back to austenite at the typical human body temperature of about 36.7°C (98°F). Other materials suitable for forming the inner layer 32 include copper-tin, copper-zinc, copper-zinc-tin, copper-zinc-xenon, copper-aluminum-nickel, copper-gold-zinc, gold-cadmium, gold-copper-zinc, iron beryllium (Fe_3Be), iron platinum (Fe_3Pt), indium-thallium, iron-manganese, iron-nickel-titanium-cobalt, nickel-titanium-vanadium, and silver-cadmium. Examples of superelastic and shape memory alloys are found in U.S. Patent No. 4,035,007 to Harrison et al., U.S. Patent No. 4,144,057 to Melton et al., U.S. Patent No. 4,505,767 to Quin, U.S. Patent No. 4,894,100 to Yamauchi, U.S. Patent No. 5,114,504 to AbuJudom et al., and U.S. Patent No. 5,641,364 to Goldberg.

With reference now to FIG. 2, when the inner layer 32 and the outer layer 30 have been joined together to form the body 10, the final stent is manufactured by cutting out a pattern through the outer and inner layers to form radially expandable elements 50 connected to adjacent elements by interconnecting members 52. Numerous patterns may be cut into the body 10 to form an expandable stent, and FIG. 3 shows an alternative embodiment of such a pattern. Co-owned U.S. Patent No. 5,514,154 to Lau et al., U.S. Patent No. 5,569,295 to Lam, U.S. Patent No. 5,591,197 to Orth et al., U.S. Patent No. 5,603,721 to Lau et al., U.S. Patent No. 5,649,952 to Lam, U.S. Patent No. 5,728,158 to Lau et al., and U.S. Patent No. 5,735,893 to Lau et al. describe such radially expandable stent patterns.

With continued reference to FIGS. 2 and 3, expandable elements 50 and 60 preferably are formed out of the body 10 through a laser cutting process, such as the process described in the previously referenced patents, as well as commonly owned U.S. Patent No. 5,759,192 to Saunders. Another preferred method involves chemically etching the tube 10, such as by the process described in U.S. Patent No. 5,735,893 to Lau et al. referenced above.

It will be apparent from the foregoing that the present invention provides a new and improved stent for maintaining the patency of a body lumen while offering superior resistance to permanent deformation. While the invention has been illustrated and described herein in terms of its use as an intravascular stent, it will be apparent to those

skilled in the art that the stent structure disclosed herein can be used to manufacture other types of expandable intravascular devices, such as grafts, filters, and the like. Additionally, the scope of the invention is not limited to a stent with only one layer each of malleable metal and elastic alloy, but rather encompasses the use of tubular structured comprised of multiple layers of such malleable metals and elastic alloys to form stents and other such devices. The invention also is not limited to solely the disclosed methods for fitting and/or bonding the layers together, which are merely illustrative of the many practicable possibilities. Further modifications and improvements also may be made without departing from the scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED IS:

1. A stent for implanting and expanding in a body lumen, comprising:

an outer layer formed from a biocompatible, malleable metal and defining a tubular, radially expandable body; and

an inner layer formed from a superelastic metal and disposed within the outer layer to define a longitudinal lumen through the tubular body.

2. The stent of claim 1, wherein the malleable metal is selected from the group consisting of stainless steel, cobalt, platinum, iridium, gold, magnesium, titanium, tantalum, and platinum-iridium alloys.

3. The stent of claim 1, wherein the superelastic metal is selected from the group of alloys consisting of copper-tin, copper-zinc, copper-zinc-aluminum, copper-zinc-tin, copper-zinc-xenon, copper-aluminum-nickel, copper-gold-zinc, gold-cadmium, gold-copper-zinc, iron beryllium (Fe_3Be), iron platinum (Fe_3Pt), indium-thallium, iron-manganese, iron-nickel-titanium-cobalt, nickel-titanium, nickel-titanium-vanadium, and silver-cadmium.

4. The stent of claim 1, wherein the outer layer and the inner layer are co-drawn to form a unitary tube defining the tubular body.

5. The stent of claim 1, wherein the inner layer and the outer layer are co-drawn to form the tubular body.

6. The stent of claim 1, wherein the inner layer is bonded to the outer layer to form the tubular body.

7. The stent of claim 1, wherein the outer layer is compressed onto the inner layer thereby forming an interference fit to form the tubular body.

8. The stent of claim 1, further comprising a plurality of expandable elements defined by laser cuts made in the tubular body.

9. A stent for implanting in a body lumen, comprising:

at least one layer formed from a biocompatible, malleable metal with an outer surface and an inner surface to define a tubular, radially expandable body; and

at least one layer formed from a superelastic metal and bonded to one of the surfaces of the at least one malleable metal layer.

10. The stent of claim 9, wherein the malleable metal is selected from the group consisting of stainless steel, cobalt, platinum, iridium, gold, magnesium, titanium, tantalum, and platinum-iridium alloys.

11. The stent of claim 9, wherein the superelastic metal is selected from the group of alloys consisting of copper-tin, copper-zinc, copper-zinc-aluminum, copper-zinc-tin, copper-zinc-xenon, copper-aluminum-nickel, copper-gold-zinc, gold-cadmium, gold-copper-zinc, iron beryllium (Fe_3Be), iron platinum (Fe_3Pt), indium-thallium, iron-manganese, iron-nickel-titanium-cobalt, nickel-titanium, nickel-titanium-vanadium, and silver-cadmium.

12. The stent of claim 9, further comprising a plurality of expandable elements defined by openings formed in the tubular body.

13. A stent for implanting in a body lumen, comprising:

alternating layers formed from a first biocompatible, malleable metal and a second, super elastic metal and disposed within one another to define a tubular, radially expandable body with a longitudinal lumen extending therethrough.

14. The stent of claim 13, wherein the malleable metal is selected from the group consisting of stainless steel, cobalt, platinum, iridium, gold, magnesium, titanium, tantalum, and platinum-iridium alloys.

15. The stent of claim 13, wherein the superelastic metal is selected from the group of alloys consisting of copper-tin, copper-zinc, copper-zinc-aluminum, copper-zinc-tin, copper-zinc-xenon, copper-aluminum-nickel, copper-gold-zinc, gold-cadmium, gold-copper-zinc, iron beryllium (Fe_3Be), iron platinum (Fe_3Pt), indium-thallium, iron-manganese, iron-nickel-titanium-cobalt, nickel-titanium, nickel-titanium-vanadium, and silver-cadmium.

16. The stent of claim 13, wherein the alternating layers are co-drawn as a unitary tube to define the expandable body.

17. The stent of claim 13, wherein the alternating layers are compressed together, thereby forming an interference fit to form the tubular body.

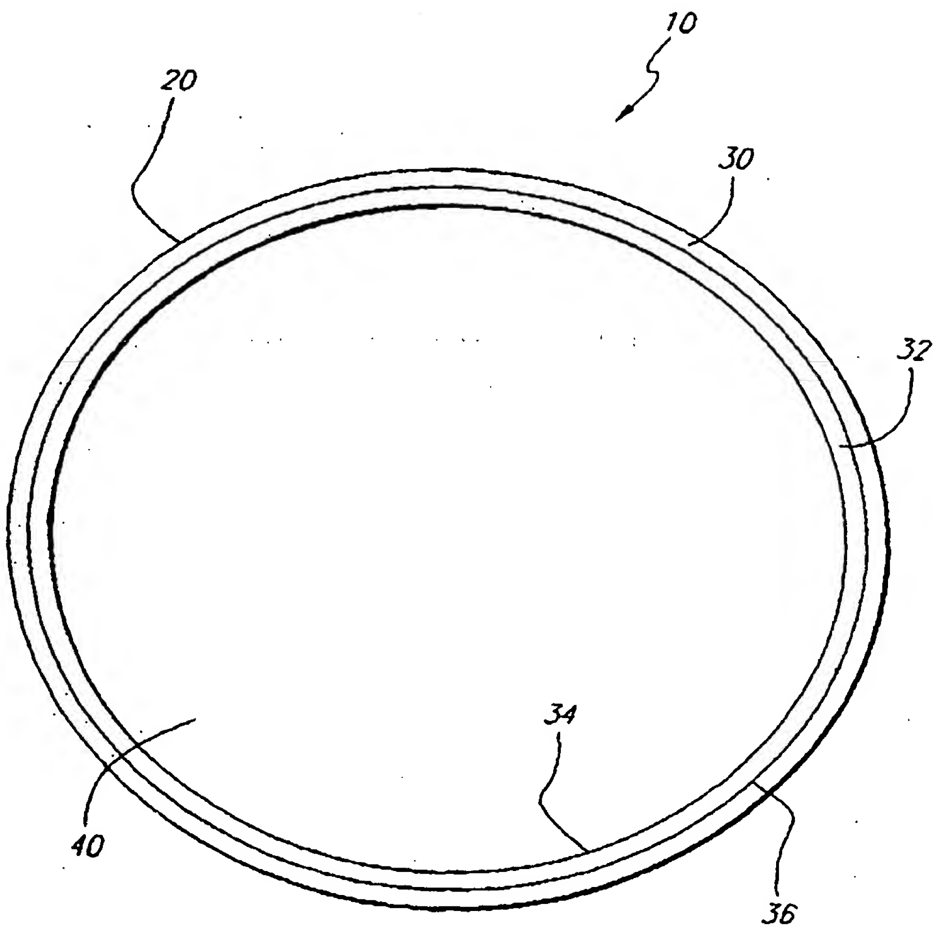


FIG. 1

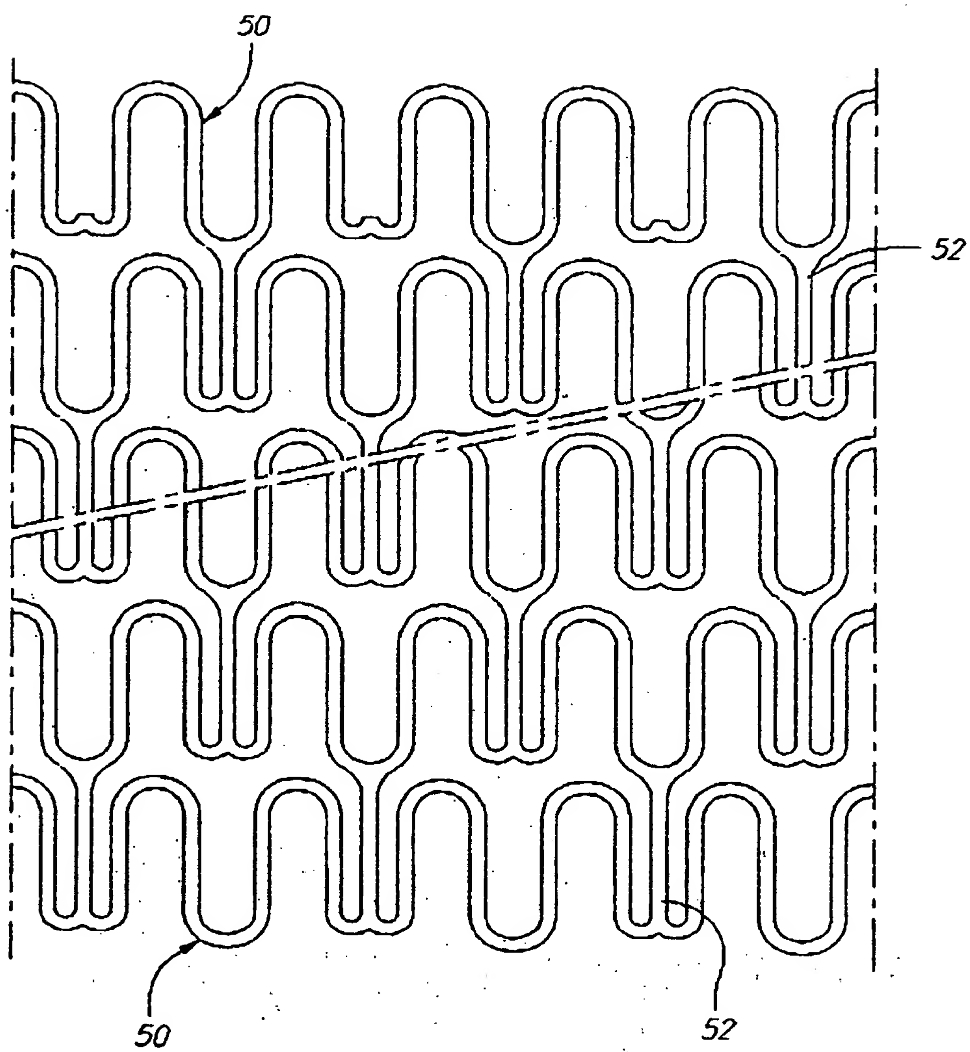
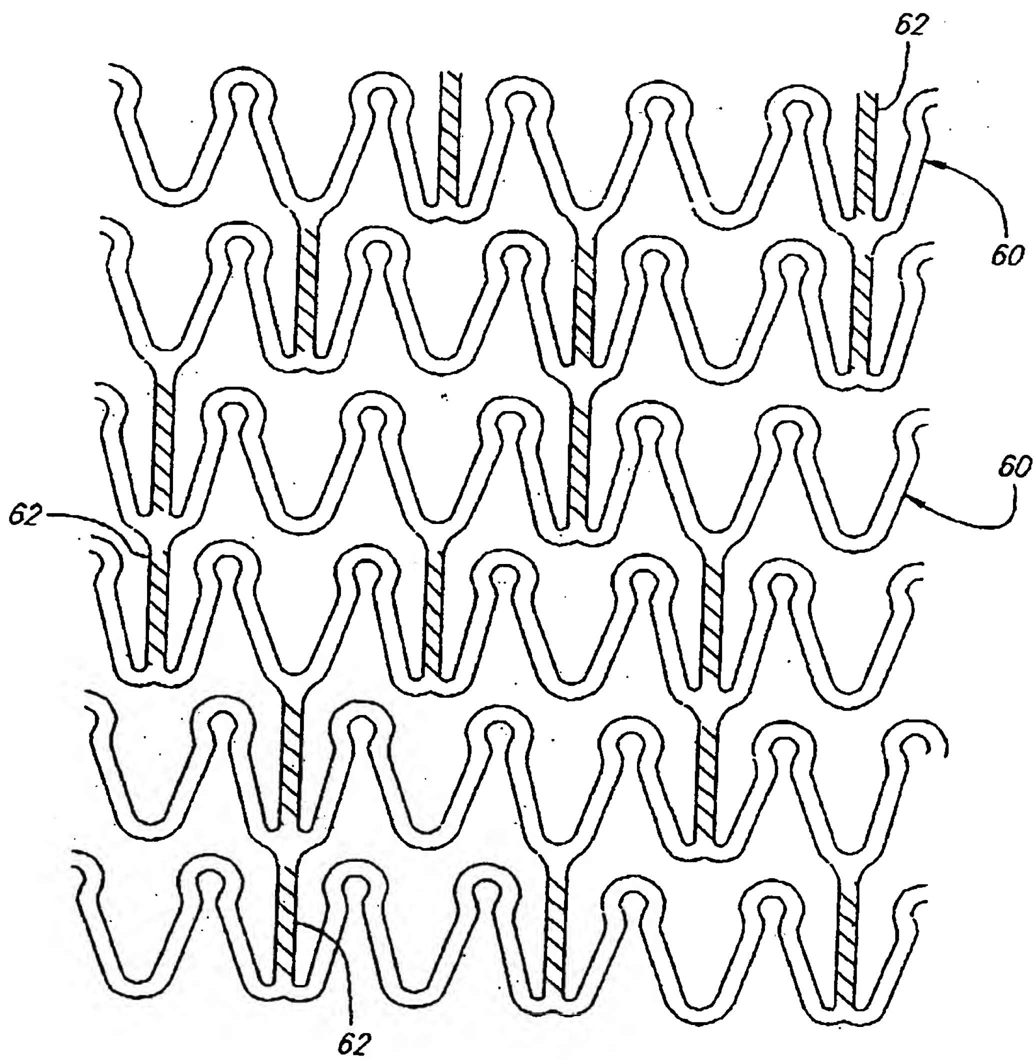


FIG. 2

FIG. 3



INTERNATIONAL SEARCH REPORT

Inte .onal Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L27/04 A61L27/06 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 824 900 A (ADVANCED CARDIOVASCULAR SYSTEM) 25 February 1998 (1998-02-25) column 1, line 45 -column 2, line 35 column 4, line 8 - line 23 column 4, line 51 -column 5, line 8 ---	1-3,8-15
X	EP 0 809 998 A (CORDIS CORP) 3 December 1997 (1997-12-03) page 2, line 58 -page 3, line 9 page 6, line 36 - line 44 ---	1-4, 9-11, 13-15
P,X	EP 0 951 877 A (CORDIS CORP) 27 October 1999 (1999-10-27) column 5, line 20 -column 6, line 5 column 6, line 24 - line 47 figures 1-3 --- -/--	1-17

[X] Further documents are listed in the continuation of box C.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 540 290 A (ADVANCED CARDIOVASCULAR SYSTEM) 5 May 1993 (1993-05-05) abstract column 1, line 37 -column 2, line 14 column 2, line 40 - line 56 column 7, line 23 - line 50 -----	1-17

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/04987

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
EP 0824900	A	25-02-1998	AU	7177996	A	26-02-1998
			CA	2190696	A	23-02-1998
			JP	10080492	A	31-03-1998
			NZ	299738	A	24-06-1997
EP 0809998	A	03-12-1997	US	5733326	A	31-03-1998
			CA	2205194	A	28-11-1997
			JP	10099445	A	21-04-1998
			US	6027528	A	22-02-2000
EP 0951877	A	27-10-1999	AU	2384899	A	28-10-1999
			JP	11332998	A	07-12-1999
EP 0540290	A	05-05-1993	CA	2079417	A	29-04-1993
			DE	69224262	D	05-03-1998
			DE	69224262	T	14-05-1998
			DE	69229751	D	09-09-1999
			DE	69229751	T	02-12-1999
			DE	540290	T	05-06-1997
			DE	734699	T	05-06-1997
			EP	0734699	A	02-10-1996
			EP	0807424	A	19-11-1997
			JP	2645203	B	25-08-1997
			JP	6181993	A	05-07-1994
			US	6066168	A	23-05-2000
			US	6066167	A	23-05-2000
			US	6056776	A	02-05-2000
			US	5421955	A	06-06-1995
			US	5514154	A	07-05-1996
			US	5603721	A	18-02-1997
			US	5728158	A	17-03-1998
			US	5735893	A	07-04-1998
			US	5766238	A	16-06-1998